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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,362	01/08/2004	James Weldon	29985/03-006	7606

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CHICAGO, IL 60606

EXAMINER

NEAL, TIMOTHY J

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/754,362

Applicant(s)

WELDON ET AL.

Examiner

Timothy J. Neal

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/20/04 5/20/05.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24, 25, 36, 37, 42, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Frazier et al. (US 2001/00394436).

Frazier discloses:

Claim 24: A method of fixing an implantable device to a wall of a body cavity, comprising: advancing a plurality of resilient delivery members in the implantable device in the body cavity; radially expanding the delivery members to urge the implantable device against the wall of the body cavity; and advancing a fixation component from within each of the delivery members, a portion of each fixation component piercing the implantable device and the wall of the body cavity (Fig 12).

Claim 25: radially expanding comprises: removing the delivery members from within a delivery sheath, to allow the delivery members to move to a radially expanded position (Fig 2 Item 30 and Item 36).

Claim 36: each delivery member includes an associated channel therethrough and a slot communicating from the channel to an exterior of the associated delivery member, and wherein advancing a fixation component comprises: advancing pairs of

needles, attached with a length of suture material, through the channels in adjacent delivery members (Fig 13 and Paragraph 89).

Claim 37: advancing pairs of needles comprises: advancing the needles through the implantable device and the walls of the body cavity (Fig 12).

Claim 42: loading the implantable device about the delivery members, prior to advancing (Paragraph 89).

Claim 43: folding the implantable device about the delivery members at substantially uniformly spaced locations along the inner periphery of the implantable device (Paragraph 89).

Claims 24, 25, 27-34, 42-44, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller (WO 02/17797).

Miller discloses:

Claim 24: A method of fixing an implantable device to a wall of a body cavity, comprising: advancing a plurality of resilient delivery members in the implantable device in the body cavity (Fig 13); radially expanding the delivery members to urge the implantable device against the wall of the body cavity (Fig 13); and advancing a fixation component from within each of the delivery members, a portion of each fixation component piercing the implantable device and the wall of the body cavity (Page 45 Line 20 and Fig 13).

Claim 25: radially expanding comprises: removing the delivery members from within a delivery sheath, to allow the delivery members to move to a radially expanded position (Fig 12 Item 220).

Claim 27: advancing a plurality of resilient delivery members comprises: advancing a tracking sheath to a treatment site in the body cavity; and advancing the implantable device, along with the tracking sheath, to the treatment site (Fig 10 Item 235).

Claim 28: advancing a plurality of resilient delivery members comprises: sliding the plurality of delivery members in tracking relation to the tracking sheath to the treatment site (Page 47 Lines 1-3).

Claim 29: the implantable device includes a vascular graft and wherein sliding the plurality of delivery members comprises: unwrapping the vascular graft to allow radial expansion of an end of the vascular graft (Fig 18).

Claim 30: sliding the plurality of delivery members comprises: advancing the delivery members within the vascular graft (Fig 16).

Claim 31: advancing the implantable device comprises: maintaining a connection between the tracking sheath and a distal end of the vascular graft; and releasing the connection prior to radially expanding the delivery members (Fig 18).

Claim 32: prior to removing the delivery members from the delivery sheath, expanding an expandable member to urge the implantable device against the wall of the body cavity (Fig 15 Item 230).

Claim 33: the expandable member comprises an inflatable member and wherein expanding the expandable member comprises: inflating the inflatable member to exert radially directed pressure on the implantable device against the wall of the body cavity (Fig 15 Item 230).

Claim 34: expanding an expandable member comprises: expanding the expandable member into a shape conforming to a shape of the radially expanded delivery members (Fig 15 Item 230).

Claim 42: loading the implantable device about the delivery members, prior to advancing (Fig 16).

Claim 43: loading comprises: folding the implantable device about the delivery members at substantially uniformly spaced locations along the inner periphery of the implantable device (Fig 16 Item 225).

Claim 44: A fixation system for affixing a vascular graft to a wall of a blood vessel across an aneurysm, comprising: an array of delivery tubes advancable through the graft and movable between a radially contracted position and a deployment position in which ends of the delivery tubes expand radially to urge the graft against the wall (Fig 13 Item 215); and a plurality of fixation components, one component slidably disposed in each delivery tube, the fixation components slidable out of the delivery tubes to connect the graft to the wall of the blood vessel (Fig 14 Item 250).

Claim 46: a delivery sheath slidable over the array of delivery tubes, the delivery sheath holding the delivery tubes in the contracted position and removal of the delivery

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sheath allowing movement of the delivery tubes into the deployment position (Fig 18 Item 220).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 10-14, 22, 23, 26, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller (WO 02/17797).

Miller discloses:

Claim 1: A fixation system for fixing an implantable device in a body cavity, comprising: a plurality of resilient delivery members movable between a generally longitudinal delivery position and a radially expanded deployment position (Fig 13 Item 215), the delivery members defining a delivery channel therein with a distal opening (Fig 13 Item 215); a fixation component slidably disposed in each of the delivery channels (Fig 14 Item 250).

Claim 2: a delivery sheath slidable over the plurality of resilient delivery members (Fig 13 Item 235).

Claim 3: the delivery members define the delivery channel as a closed lumen therein with the distal opening (Fig 16 Item 215).

Claim 10: an inner sheath, the plurality of delivery members being arranged generally radially about the inner sheath (Fig 12 Item 220).

Claim 11: the implantable device comprises: a vascular graft (Page 37 Line 10).

Claim 12: a releasable fixation member releasably fixing the vascular graft to a distal end of the inner sheath (Fig 16 Item 235).

Claim 13: an expandable member expandable from a contracted position closely proximate an exterior of the delivery sheath to an expanded position urging the vascular graft against the wall of the body cavity (Fig 15 Item 210).

Claim 14: the expandable member is positioned at a distal end of the delivery sheath (Fig 10 Item 210).

Claim 22: the body cavity comprises a vascular lumen in a region of an aneurysm (Page 26 Line 20).

Claim 23: the delivery members are configured to exert outwardly directed pressure on an inner wall of the implantable device at substantially uniformly spaced areas, when in the deployed position (Fig 13 Item 215).

Claims 1 and 45: Miller does not explicitly disclose a pusher slidably disposed in each of the delivery channels to push the fixation component in each delivery channel. However, Miller does show a pusher slidably disposed in one delivery channel to push the fixation component in the delivery channel (Fig 5A Item 52). That particular figure is only directed at one pusher, one fixation component, and one delivery channel. Miller does further describe multiple delivery channels with fixation components disposed therein (Fig 14 Item 250). Therefore, it would have been obvious to a person having

ordinary skill in the art at the time the invention was made to modify Miller's pusher assembly to include a pusher for each of the delivery tubes. Such a modification would allow the fixation members to be released from the delivery channels.

Claim 26: Miller also does not disclose sliding a plunger in each of the delivery members to push the fixation components in the delivery members. As stated above, Miller does describe pushing the plunger to release the fixation components. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Miller's pusher assembly to include a pusher for each of the delivery tubes. Such a modification would allow the fixation members to be released from the delivery channels.

Claims 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller (WO 02/17797) in view of Hlavka et al. (US 2004/0172046).

Miller discloses the invention substantially as claimed as stated above. Miller further discloses:

Claim 5: the delivery members, when in the deployed position, urge the implantable device against a wall of the body cavity (Fig 19).

Claim 6: the first fixation member is disposed to pierce the implantable device and a wall of the body cavity when advanced from the delivery channel by the pusher (Fig 15 Item 250).

Claim 7: the first fixation member has a sharpened end for piercing the implantable device and body cavity wall (Fig 2 Item 21).

Claim 8: the first and second fixation members are arranged in a generally longitudinally aligned orientation when in the delivery channel (Fig 5A Item 10).

Claim 9: one of the first and second fixation members are releasably connected to the pusher (Fig 5A-F).

Miller does not disclose each fixation component comprises: a first fixation member; a second fixation member; and a tether connecting the first and second fixation members.

Hlavka teaches each fixation component comprises: a first fixation member; a second fixation member; and a tether connecting the first and second fixation members (Fig 10a Items 904 and 905). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Miller's fixation system to include Hlavka's fixation member and tether. Such a modification would allow the two members to be pulled against one another with the tissue and/or graft between them, thus securing the graft to the tissue.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller (WO 02/17797) in view of Frazier et al. (US 2001/00394436).

Miller discloses the invention substantially as claimed as stated above.

Miller does not disclose the expandable member has a distal end thereof shaped in the expanded position to conform to a shape of the delivery members in the deployment position.

Frazier teaches the expandable member has a distal end thereof shaped in the expanded position to conform to a shape of the delivery members in the deployment position (Paragraph 62). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Miller's fixation system to include Frazier's expandable member. Such a modification would provide a means for expanding the delivery members.

Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller (WO 02/17797) in view of Starksen et al. (US 2004/0193191).

Miller discloses the invention substantially as claimed as stated above.

Miller does not disclose each of the delivery members define an associated delivery channel as a channel having a slot communicating with an exterior of the delivery member; the fixation component comprises: a piercing member with a tether attached thereto; pairs of piercing members in adjacent delivery members are tethered together by the tether; the tether is oriented to ride through the slots in the adjacent delivery members as the pushers advance the piercing members through the channel in the delivery members; the pairs of piercing members are advanced through the implantable device and through a wall of the body cavity, the piercing members pulling ends of the tether through the implantable device and through the wall of the body cavity.

Starksen teaches each of the delivery members define an associated delivery channel as a channel having a slot communicating with an exterior of the delivery

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member (Fig 9A Item 528); the fixation component comprises: a piercing member with a tether attached thereto (Fig 9B Item 534); pairs of piercing members in adjacent delivery members are tethered together by the tether (Fig 9B Item 534); the tether is oriented to ride through the slots in the adjacent delivery members as the pushers advance the piercing members through the channel in the delivery members (Fig 9B Item 534); the pairs of piercing members are advanced through the implantable device and through a wall of the body cavity, the piercing members pulling ends of the tether through the implantable device and through the wall of the body cavity (the Examiner considers "are advanced through the implantable device and through a wall of the body cavity, the piercing members pulling ends of the tether through the implantable device and through the wall of the body cavity" to be functional language directed at an intended use and therefore gives the clause no weight; Fig 9A Item 526 are directed at the piercing members).

Claims 21 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller (WO 02/17797) in view of Ginn (US 6,645,205).

Miller discloses the invention substantially as claimed as stated above.

Claim 21: Miller does not disclose a radio frequency (RF) energy source connected to the pushers to apply RF energy to a wall of the body cavity through the pushers and the fixation components.

Ginn teaches a radio frequency (RF) energy source connected to a device to apply RF energy to a wall of the body cavity through the device (Fig 12). Therefore, it

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would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Miller's fixation system to include Ginn's RF source. Such a modification would allow the system to apply RF energy to the tissue. One may want to apply RF to fuse tissue.

Claim 35: Miller does not disclose applying radio frequency (RF) energy to the wall of the body cavity through the fixation component prior to piercing the implantable device.

Ginn teaches applying a radio frequency (RF) energy source connected to a device to apply RF energy to a wall of the body cavity through the device (Fig 12). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Miller's fixation system to include Ginn's RF source. Such a modification would allow the system to apply RF energy to the tissue. One may want to apply RF to fuse tissue.

Claims 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al. (US 2001/0039436).

Frazier discloses the invention substantially as claimed as stated above. Frazier further discloses laparoscopically accessing a treatment site external to the body cavity (Paragraph 10, the Examiner considers laparoscopy to be substantially equivalent to endoscopic and thoracoscopic procedures); the delivery members comprise a plurality of pairs of delivery members and wherein advancing pairs of needles comprises: advancing a plurality of pairs of needles through the channels (Fig 13); tying a plurality

of knots in a plurality of ends of suture material carried by the plurality of pairs of needles (Paragraph 89).

Frazier does not directly disclose tying ends of the suture material carried by the needles, external to the body cavity. However, Frazier discloses the use of sutures; therefore, it is well within the purview of a person having ordinary skill in the art at the time the invention was made to tie ends of suture material external to the body cavity. Such a modification would allow the surgeon to tie the sutures without having to further open the vessel or having to perform the tying within the confined space of the vessel.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

8/20/06